IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

C.A. No. 1:17-CV-217 (Keeley)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead" or "Plaintiff") brings this Complaint for patent infringement against Defendant Mylan Pharmaceuticals Inc. ("Mylan") and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement by Mylan of U.S. Patent No. 8,148,374 ("the '374 Patent"), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly, 35 U.S.C. §§ 271(a), (b), (c), (e), and 281. This action relates to the Abbreviated New Drug Application ("ANDA") No. 211124, filed by Mylan with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Bristol-Myers Squibb's Evotaz® (atazanavir and cobicistat tablets in a dosage strength of 300 mg atazanavir/150 mg cobicistat) drug product prior to the expiration of the '374 Patent.

PARTIES

2. Plaintiff Gilead Sciences, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market.

4. On information and belief, and consistent with its practice with respect to other generic products, Mylan will act to distribute and sell its generic atazanavir and cobicistat tablet drug product that is the subject of ANDA No. 211124 ("Defendant's ANDA Product") throughout the United States, including within West Virginia. On information and belief, Mylan knows and intends that Defendant's ANDA Product will be distributed and sold in the United States, including within West Virginia.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. On information and belief, this Court has personal jurisdiction over Mylan because Mylan has purposefully availed itself of the benefits and protections of West Virginia's laws such that Mylan should reasonably anticipate being haled into court in West Virginia. On information and belief, Mylan has had persistent and continuous contacts within this judicial district, including developing, manufacturing, and/or selling pharmaceutical products that are sold in this judicial district.

7. On information and belief, Mylan is incorporated under the laws of West Virginia, has its principle place of business at 781 Chestnut Ridge Road, Morgantown, West

Virginia 26505, and is therefore "at home" in West Virginia and subject to suit in this judicial district.

8. On information and belief, Mylan is registered to do business in West Virginia (Organization Identification #20402), and has thereby consented to suit in West Virginia.

9. On information and belief, Mylan has appointed Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302 as its registered agent for receipt and service of process.

10. On information and belief, Mylan derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

12. On April 3, 2012, the United States Patent and Trademark Office issued the '374 Patent, entitled "Modulators of Pharmacokinetic Properties of Therapeutics." A true and correct copy of the '374 Patent is attached hereto as Exhibit A.

13. Plaintiff Gilead Sciences, Inc. is the assignee of the '374 Patent, and holds title to the '374 Patent.

14. The '374 Patent claims compounds (along with their stereoisomers) and their associated salts and compositions, as well as methods for using the compounds. Cobicistat is one of the compounds claimed in the '374 Patent.

15. Bristol Myers-Squibb Co. is the holder of approved New Drug Application ("NDA") No. 206353 for 300 mg atazanavir/150 mg cobicistat tablets, which is sold under the trade name Evotaz®. Evotaz® is a combination human immunodeficiency virus (HIV-1) protease

inhibitor (atazanavir) and CYP3A inhibitor (cobicistat) indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection.

16. Evotaz® is included in FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs in the Orange Book may be used as the basis of an applicant's ANDA to obtain approval of the generic drug product under the provisions of 21 U.S.C. § 355(j).

17. The Orange Book lists patents that the NDA holder asserts cover the approved drug product. The '374 Patent is listed in the Orange Book in association with Evotaz®. The '374 Patent claims cover Evotaz®.

18. On information and belief, Mylan submitted ANDA No. 211124 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product—a generic version of Evotaz®.

19. On information and belief, Mylan continues to seek approval of ANDA No. 211124 from the FDA and intends to engage in the marketing, commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product (including the commercial marketing and sale of Defendant's ANDA Product in the State of West Virginia) if the FDA approves ANDA No. 211124.

20. On November 7, 2017, Plaintiff received a letter dated November 6, 2017 (Mylan's "Paragraph IV Letter") purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto, and stating that Mylan had submitted ANDA No. 211124 seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Defendant's ANDA Product prior to the expiration of the '374 Patent.

21. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), Mylan's Paragraph IV Letter shall contain "a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed."

22. Mylan's Paragraph IV Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '374 Patent is invalid.

23. Mylan's Paragraph IV Letter does not state that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product would not infringe the claims of the '374 Patent, if valid. Mylan's only statement of non-infringement is based on a presumed finding of invalidity.

24. On information and belief, Mylan had actual and constructive notice of the '374 Patent prior to the filing of ANDA No. 211124.

25. Mylan's Paragraph IV Letter states that the compound of claim 1 of the '374 Patent is cobicistat and that Defendant's ANDA Product contains the active ingredient cobicistat.

26. Plaintiff Gilead Sciences, Inc. commenced this action within forty-five days of the date on which it received Mylan's Paragraph IV Letter containing Mylan's Paragraph IV certifications.

COUNT I

(Infringement of the '374 Patent under 35 U.S.C. § 271(e))

27. Plaintiff incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

28. On information and belief, Mylan submitted ANDA No. 211124 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product before the expiration of the '374 Patent.

29. On information and belief, Mylan made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '374 Patent is invalid or unenforceable.

30. Under 35 U.S.C. § 271(e)(2), Mylan has infringed the '374 Patent by submitting ANDA No. 211124 with a Paragraph IV certification and seeking FDA approval to market Defendant's ANDA Product prior to the expiration of the '374 Patent.

31. Upon information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product prior to the expiration of the '374 Patent would infringe, contribute to the infringement of, and/or induce the infringement of claims 1-10 of the '374 Patent, either literally or under the doctrine of equivalents.

32. Mylan's Paragraph IV Letter does not state that Defendant's ANDA Product, or its use, will not infringe the claims of the '374 Patent, if valid.

33. Mylan had actual and constructive notice of the '374 Patent prior to filing ANDA No. 211124.

34. Plaintiff holds title to the '374 Patent.

35. Plaintiff has no adequate remedy at law to redress the infringement by Mylan.

36. Plaintiff will be irreparably harmed if Mylan is not enjoined from infringing, actively inducing, or contributing to the infringement of the '374 Patent, either literally or under the doctrine of equivalents.

37. Plaintiff respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Mylan's ANDA No. 211124 shall be a date which is not earlier than the current expiration date of the '374 Patent and any additional periods of exclusivity.

COUNT II

(Declaratory Judgment of Infringement of the '374 Patent)

38. Plaintiff incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

39. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

40. Mylan has knowledge of the '374 Patent.

41. On information and belief, Mylan has acted with full knowledge of the '374 Patent and without a reasonable basis for believing that it would not be liable for infringing, actively inducing, or contributing to the infringement of the '374 Patent.

42. On information and belief, Mylan submitted ANDA No. 211124 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product before the expiration of the '374 Patent.

43. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product will infringe the '374 Patent, either literally or under the doctrine of equivalents.

44. On information and belief, Defendant's ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '374 Patent, either literally or under the doctrine of equivalents.

45. On information and belief, Mylan's marketing, commercial manufacture, use, offer for sale, sale and/or importation of Defendant's ANDA Product will infringe one or more

claims of the '374 Patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents.

46. Plaintiff has no adequate remedy at law to redress Mylan's infringing activities.

47. Plaintiff will be irreparably harmed if Mylan is not enjoined from infringing, actively inducing, or contributing to the infringement of the '374 Patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. a judgment that Mylan has infringed one or more claims of the '374 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents;

B. a judgment pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Mylan's ANDA No. 211124 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration date of the '374 Patent, including any additional exclusivity period applicable to that patent;

C. a judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Product described in ANDA No. 211124 would constitute infringement by Mylan of the '374 Patent, or actively induce and/or contribute to infringement by others, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

D. a judgment permanently enjoining Mylan and each of its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendant's ANDA Product until the day after the expiration of the '374

Patent, including any additional exclusivity period applicable to that patent, and from otherwise infringing one or more claims of the '374 Patent, either literally or under the doctrine of equivalents;

E. damages from Mylan for any commercial activity constituting infringement of the '374 Patent, or inducing or contributing to such infringement, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c), either literally or under the doctrine of equivalents;

F. a declaration that this case is exceptional;

G. an award of Plaintiff's costs, expenses, reasonable attorneys' fees, and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

H. such other and further relief as the Court may deem just and proper.

Respectfully Submitted,

/s/Chad L. Taylor

Frank E. Simmerman, Jr. (WV Bar #3403)
Chad L. Taylor (WV Bar #10564)
Frank E. Simmerman, III (WV Bar #11589)
SIMMERMAN LAW OFFICE, PLLC
254 East Main Street
Clarksburg, West Virginia 26301
(304) 623-4900

Attorneys for Plaintiff Gilead Sciences, Inc.

OF COUNSEL:

Adam K. Mortara
J. Scott McBride
Nevin M. Gewertz
Rebecca T. Horwitz
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

Meg E. Fasulo
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
1801 Wewatta Street, Suite 1200
Denver, CO 80202
(303) 592-3100

December 15, 2017